GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3643
ANSWERED ON:12.12.2001
ANTI CANCER DRUG
BASUDEB ACHARIA

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether an anti-cancer drug call Grasim launched into the market during July 2001 has been withdrawn from the market; and

(b) if so, the reasons therefor?

Answer

MINISTER OF HEALTH AND FAMILY WELFARE(DR. C.P. THAKUR)

(a) & (b) No Sir, M/s. Nicholas Piramal India Ltd. (NPIL), Mumbai had moved the MRTP Commission urging it to ask Dr. Reddy`s Lab., Hyderabad to withdraw r-GCSF (Grastim) injection stocks and stop sales of the product as NPIL alleged that the package insert of Grastim contains false and misleading statements. Similar representation was also made to Drugs Controller General of India.

Consequent to the representation, M/s. Dr. Reddy`s Laboratory, Hyderabad was directed to submit fresh revised package insert of Grastim and to replace the existing package insert. Dr. Reddy`s Laboratory, Hyderabad then submitted revised version of package insert after deleting the objectionable matter and the same was approved.

NPIL then represented that the International non-proprietary name Filgrastim used by Dr. Reddy`s Laboratory is incorrect, as their r-GCSF is not exactly the same as Filgrastim, which is being manufactured by M/s. Roche and marketed by M/s. NPIL.Since the field of bigenerics is new and complex one, the matter has been referred for examination by an expert committee.